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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,941	07/17/2003	Peter Gingras	14188-002001	1557

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EXAMINER

SWEET, THOMAS

ART UNIT	PAPER NUMBER
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3738

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/621,941

Applicant(s)

GINGRAS, PETER

Examiner

Thomas J. Sweet

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 14-84 is/are pending in the application.
- 4a) Of the above claim(s) 4-7 and 26-84 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 8-10, 12 and 14-25 is/are rejected.
- 7) ☒ Claim(s) 11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/2/06 + 1/17/07</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I species GG, claims 1-3, 8-12 and 14-25 in the reply filed on 1/17/2007 is acknowledged. Claim 1 is generic.

Response to Arguments

Applicant's arguments, see page 14, filed 05/05/2006, with respect to 35 USC 112 (2) have been fully considered and are persuasive. The rejection of claims 1-12 and 14-25 under 35 USC 112 (2) has been withdrawn, In view of the special definition set out in the disclosure.

Applicant's arguments with respect to claims 1-12 and 14-25 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 12 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are no in the accepted Markush form of "selected from the group consisting of...and...". The use of the term "comprising" renders the scope of claim 3 uncertain. The use of the term "wherein" renders the scope of claims 12 and 15 uncertain.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 15 recites the broad recitation less than .014 inches, and the claim also recites less than .013 inches, etc., which is the narrower statement of the range/limitation.

Claims 22-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claim relates structure to an unknown ("do not restrict tissue movement" and "the structure being repaired"). This claim also appear to be an omnibus type claim.

Art Unit: 3738

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 8-10, 12, 14-16, 18-21 and 25 rejected under 35 U.S.C. 102(b) as being anticipated by Forst et al (US 6071291). Forst et al discloses a non-woven soft tissue (soft tissue commingles with the implant) implant (fig. 1) comprising a porous biocompatible film (abs) having a plurality of cells (12), a thickness of less than about 0.015 inches (col 2, lines 64-65), and a surface area ratio less than 1.5 (as shown the 2d surface covers less than half the area, so twice that plus the thickness is about a surface area ration of 1- additionally, there are disclosed size ranges with enough specificity to anticipate the range), wherein each of the cells in the plurality of cells has a plurality of undulating elements (col 2, lines 10-13).

With regards to claims 9 and 10, wherein one or more of the cells in the plurality of cells has a diameter, measured along the longest axis of the cell, of about 1,500 microns to about 5,000 microns (col 3, lines 38-42, $2\text{ mm} + (2\text{ to }1.5) \cdot 3\text{ mm}$ width corresponding to thickness = approx. 2500 microns).

With regards to claim 12, one or more of the cells of the plurality are essentially square, rectangular, or diamond-shaped (col 2, lines 27-31).

With regards to claim 14, wherein one or more of the cells of the plurality have essentially the same shape as the cell shown in Mesh2, Mesh2C, Mesh3, or Mesh4 (fig. 1).

With regards to claim 16, the porous biocompatible film has atraumatic edges (col 4, lines 16-21).

With regards to claim 18, the implant is flexible along two axes (col 4, lines 43-48).

With regards to claims 19-21 and 25, the undulating elements are in phase (as shown in fig 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 17 and 22 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Forst et al.

With regards to claim 17, the porous biocompatible film is at least about 2.5 cm long along a first side and no more than about 45.0 cm long along a second side (see fig. 2). The implant can be sized to the repair.

With regards to claim 22, the cells in the plurality of cells have a diameter greater than 50 microns and the non-woven soft tissue implant has force displacement characteristics that do not restrict tissue movement (the tissue can move over the implant and can deform with tissue).

Claims 2-3 and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Forst et al in view of Hardwick et al (US 6328765). Forst et al discloses a non-woven soft tissue implant as discussed above including specifying biocompatible tissue. However, Forst et al remains silent as to utilizing polymers such as polypropylene, silicone, etc... Hardwick et al teaches another non-woven surgical mesh (fig. 1a-1b and 3a-3c) made of polymer such as polypropylene, silicone, etc.. for the purpose of being biocompatible. It would have been obvious

to one of ordinary skill in the art at the time the invention was made to substitute the biocompatible polymer of Hardwick et al for the biocompatible material in the implant of Forst et al because such a modification amounts to mere substitution of one functionally equivalent material for another within the art of surgical meshes.

With regard to claims 23 and 24, the implant can be distended by 25% or more at 16 N/cm (as modified above the device would inherently deform as the applicants mesh since the structure and material would be identical).

Allowable Subject Matter

Claim 11 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Several references appear on the 892-form enclosed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J. Sweet whose telephone number is 571-272-4761. The examiner can normally be reached on 5:45am - 4:15pm, Tu-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

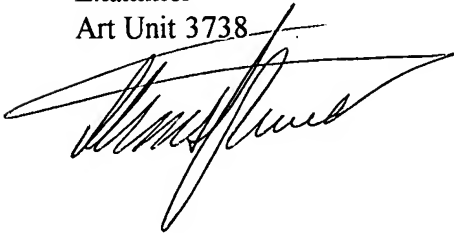
Art Unit: 3738

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thomas J Sweet

Examiner

Art Unit 3738

A handwritten signature in black ink, appearing to read 'Thomas J Sweet', written over the printed name and title.